

REMARKS

Applicants' invention involves a sterilizable composite film containing a barrier layer that is impermeable to water vapor and gases comprising a metal foil and on both sides of the barrier layer at least one functional layer. The composite film has a layer structure containing one on top of the other in the following sequence:

(a) a first functional layer containing a plastic film that is a polyester, a polyamide, or a polyolefin, or an extrusion layer of a polyolefin, or one or more lacquer layers, or print and lacquer layers, or print layers;

(b) a metal foil having a thickness of 5 to 100 μm ; and

(c) a second functional layer containing a plastic layer that is a layer comprising a coextrusion-coated, a coextruded, and/or an extrusion-laminated film having a sequence of a first polypropylene layer, a polyamide layer, and a second polypropylene layer.

The invention sterilizable composite film has a structure that can be manufactured by simple technology and can be easily processed into pouches. Also the invention sterilizable composite film can withstand sterilizable conditions without delamination.

Claims 15 to 19, 21, 22, 27 to 29, and 32 to 35 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Misasa et al. (U.S. Patent No. 4,559,266). Applicants traverse this rejection.

The Office Action stated that Misasa et al. teaches a laminated material useful for packaging materials for foodstuffs that has superior gas barrier properties, light shielding properties and moisture resistance (Abstract). Note that the Abstract of Misasa et al. states that its laminated material is "a metal-vacuum deposited layer".

Furthermore, compared to what does the laminated material of Misasa et al. have "superior" properties. Superior is a relative term. The superior properties of Misasa et al. are focused on the prior art laminated materials having a metal-vacuum deposited layer described in Misasa et al.'s prior art section. So Misasa et al.'s so-called superior properties are not relative to laminated materials containing a metal foil. A metal foil by its very definition is much thicker than a metal-vacuum deposited layer. Misasa et al. is not a very relevant reference.

The Office Action stated that the laminate comprises: an inner layer of polyolefin such as polypropylene (A); a second gas barrier layer consisting essentially of a saponified product of ethylene-vinyl acetate copolymer, polyester resin, or polyamide resin (B); a third metal layer such as aluminum (C); and a fourth outer layer such as polyester resin like PETP (Claim 1; Col. 2, lines 12 to 18; Col. 2, lines 51 to 56; and Col. 3, lines 24 to 40). Applicants traverse this statement as being factually incorrect. Layer (C) is not a "metal layer" such as aluminum. Misasa et al. does not teach or suggest layer (C) in such generic scope. According to Misasa et al., layer (C) is "a metal-vacuum deposited layer".

Applicants' invention requires a metal foil. The very definition of a metal foil excludes "a metal-vacuum deposited layer". A metal-vacuum deposited layer is much thinner than a metal foil. The properties of a metal foil are different than those of a metal-vacuum deposited layer.

Likewise, one ordinarily skilled in the art would not seek an invention using a metal foil among patents for laminated materials containing a metal-vacuum deposited layer. Misasa et al. is not a very relevant reference.

To try to substitute a metal foil in the laminated material of Misasa et al. for its metal-vacuum deposited layer would destroy the very invention specified and claimed by Misasa et al. since Misasa et al.'s invention requires an extremely thin metal layer (that has been vacuum deposited). A foil is very much thicker than the metal-vacuum deposited layer required by Misasa et al.

Applicants' specification states:

"The metal foils may have a thickness e.g. of 5 to 100 μm , ***." [Page 2, line 20]

Column 3, lines 45 to 49, of Misasa et al. sets out ratios of the relative thickness ranges for the layers of its laminated material. Extracting layer A (polyolefin layer) and layer C (metal-vacuum deposited layer) from the relative thickness ranges ratio formula, one has:

Layer A : Layer C

100 to 200 : 0.03 to 0.08

The largest thickness in the examples of Misasa et al.'s layer A is 750 μm . The relative thickness ranges ratio formula, to secure the largest thickness of layer C, becomes:

Layer A : Layer C

100 : 0.08

The largest value for Misasa et al.'s layer C is calculated as follows:

$$\frac{750 \mu\text{m}}{100} = \frac{T}{0.08}$$

$$T = 7.50 \mu\text{m} \times 0.08$$

$$T = 0.6 \mu\text{m}$$

So the metal-vacuum deposited layer of Misasa et al. is very much thinner than applicants' metal foil and is not suggestive thereof.

European Patent Application No. 0240571 (Nakamura et al.) is already of record. Table 1 of Nakamura et al. shows metal-vacuum deposited layers having thicknesses of 500 to 1000 angstroms or 0.5 to 1.0 μm . This information confirms that the metal-vacuum deposited layer of Misasa et al. is at least several times thinner than applicant's metal foil.

The Office Action stated that, in producing the laminated material, it is preferred to employ a process in which a laminated material of layers A and B and a laminated material of layers C and D are previously produced and the two laminated materials are then laminated to each other (Col. 4, lines 10 to 14). Layer C is only a metal-vacuum deposited layer.

The Office Action stated that the laminate can be formed by bonding the layers together by any suitable procedure such as extrusion lamination or dry

lamination using an adhesive coating or primer (Col. 3, line 51, to Col. 4, line 9; and the Examples). This information does not make obvious applicants' specific three layers of applicants' second functional layer (c).

The Office Action stated that the amount of adhesive coated is from 2 to 10 grams per square meter and preferably between 1.5 and 8 grams per square meter (Col. 3, lines 67, to Col. 4, line 2). This information does not cause applicants' claimed invention to be obvious.

The Office Action stated that between layer B and C may be interposed, if necessary, a suitable layer of a synthetic resin such as polyethylene or polypropylene (Col. 3, lines 20 to 24). Misasa et al. does not specifically disclose a second functional layer (c) having sequential layers of polypropylene, polyamide, and polypropylene. The choice of such specific sequence is only of many theoretical choices in Misasa et al. Even further, applicants' claims require coextrusion, coextrusion coating, and/or extrusion lamination. This extends the theoretical choices in Misasa et al. to an even larger number. No motivation is present. Misasa et al. does not suggest a composite film which fulfills all of the specifics of applicants' claims to one ordinarily skilled in the art.

The Office Action stated that laminate can be sterilized and used as a food packaging material or to form containers for packaging foods (Col. 3, lines 60 to 64; and Col. 4, lines 41 to 44). Misasa et al. only uses a metal-vacuum deposited layer. Note that Misasa et al. states:

"With laminated materials in which the above-described adhesives are placed between the metal-vacuum deposited layer and the resin layer,

heat resistance is superior and it is possible to apply a high temperature sterilizing treatment. In this case, the metal-vacuum deposited layer is stable and is not broken up.” [Col. 4, lines 36 to 41]

So Misasa et al. admits that its metal-vacuum deposited layer is unstable and breaks up during high temperature sterilizing treatment unless there is an adhesive between the metal-vacuum deposited layer and the resin layer. Applicants’ metal foil does not have such a disadvantage.

The Office Action stated that, though Misasa et al. teaches that various other polymers may be utilized for different layers other than the instantly claimed polymers, Misasa et al. does disclose the polymers instantly claimed in the order as instantly claimed, and it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize any of the polymers or polymer disclosed by Misasa et al. in the disclosed combinations to produce a multilayer composite. Applicants traverse this statement. Misasa et al. do not suggest applicants’ claimed invention. There is no motivation of record to try to piece together parts of Misasa et al. to come up with applicants’ claimed invention. The burden of proof under Section 103(a) is upon the Examiner, and the use of forbidden hindsight does not fulfill the burden.

The Office Action stated that Misasa et al. does not teach the particular thickness ranges as instantly claimed, however, it is well known in the art that the thickness of a particular layer in a multilayer composite is a result-affected variable affecting film properties such as gas and water-vapor permeability, heat-resistance, flexibility and sealing properties, and, therefore, it would have been

obvious to one having ordinary skill in the art at the time of the invention to utilize routine experimentation to determine the optimum thickness for composite layer(s) based on the desired film properties required for a particular end use, including the use of a thicker metal foil as opposed to a metal-vacuum deposited layer. Applicants traverse this statement. As shown above, Misasa et al. does not teach or suggest the use of a much thicker metal foil in place of its much narrower metal-vacuum deposited layer. Speculation does not satisfy Section 103(a). The entire object of Misasa et al. is to improve laminated materials that contain a metal-vacuum deposited layer. There is no motivation of record to substitute a metal foil for the metal-vacuum deposited layer of Misasa et al.

As to the question of the thickness of the plastic layer(s), note that the examples of Misasa et al. use polypropylene layers that have thicknesses of 350 μm and 750 μm . Applicants' polypropylene layers have an illustrative thickness range of 8 to 30 μm (page 3, lines 25 and 26) and 30 to 70 μm (page 5, lines 23 and 24). It is not obvious to one ordinarily skilled in the art to reduce the thickness of 350 μm of Misasa et al. by more than 80 percent to reach applicants' thickness. Misasa et al. states:

"Another type of laminated material which has been proposed is produced by laminating a multilayer consisting of a metal-vacuum deposited layer as an inner layer and a thermoplastic resin sheet as an outer layer on a soft type resin such as low density polyethylene by an extrusion lamination process. These materials, when produced in combination with sheets having high rigidity, suffer from disadvantages in that when they are

treated under high temperature sterilizing conditions, the metal-vacuum deposited layer is broken up, and they become unsuitable for practical use.” [Col. 1, lines 34 to 44]

Misasa et al. used a very thick polypropylene layer to try to cure the above-noted prior art problem. There is no motivation of record to destroy the Misasa et al. invention by substantially reducing the thickness of its very thick polypropylene layer.

The Office Action stated that, further, in producing multilayer composites, the use of lamination, extrusion-coating or coextrusion or combinations of these methods, with or without an adhesive between adjacent layers, are conventional and well known in the art and any combination of these methods in producing the multilayer composite taught by Misasa et al. would have been obvious to one having ordinary skill in the art at the time of the invention. Applicants traverse this statement as being mere speculation.

This rejection should be withdrawn.

Claims 15 to 19, 21, 22, 27 to 29 and 32 to 35 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al. (U.S. Patent No. 4,291,085). Applicants traverse this rejection.

The Office Action stated that Ito et al. teaches a packaging material for food to be subject to sterilization which comprises a flexible laminate sheet including a heat-sealable inner layer of polypropylene (a), an aluminum foil intermediate layer (c), an outer layer of heat-resistance thermoplastic or thermosetting resin such as the polyester PETP or a biaxially oriented film (b),

one or more impact-absorbing layers between (a) and (c) or (b) and (c), and, if necessary, adhesive or primer layers interposed between every two adjacent layers (Abstract; Col. 3, lines 35 to 45; Col. 4, lines 17 to 35; Col. 7, line 65, to Col. 8, line 18). Applicants traverse this statement as being broader than the disclosure of Ito et al. Polypropylene (a) of Ito et al. has to be a special crystalline polypropylene.

Ito et al. discloses that there can be two impact-absorbing layers between inner polypropylene layer (a) and metal foil (c). Ito et al. also discloses that its impact-absorbing layer can be a stretched, polypropylene film having at least a specified impact-absorbing coefficient, and that its impact-absorbing layer can be a polyamide film. Ito et al. does not disclose an arrangement of a polyamide film with a polypropylene film next to the metal foil.

The Examiner has the burden of proof under Section 103(a). So one question is whether or not the Examiner has factually put together a prima facie showing of obviousness. Applicants contend that question has to be answered in the negative. Further, even if a prima facie showing of obviousness is present, applicants have factually rebutted so the burden of proof is back in the Examiner's court.

Applicants' second functional layer (with specified extrusion requirements) has the layer sequence of polypropylene, polyamide and polypropylene. The first polypropylene layer faces the metal foil and the second polypropylene layer faces outward (and serves as the inner surface for the sterilizable composite film).

The special crystalline propylene (a) of Ito et al.'s comes within the scope of the second polypropylene layer of Claim 15. But applicants' further inclusion of a polyamide layer followed by a second polypropylene is unobvious over Ito et al. and in fact is directed away from applicants' invention by Ito et al.

In discussing its impact-absorbing layer(s), Ito et al. states:

"A stretched polypropylene film having an impact-absorbing coefficient within the above-mentioned range can be used as the impact-absorbing layer, but an ordinary unstretched polypropylene film or a stretched polypropylene film having an impact-absorbing coefficient outside the specified range does not function as an impact-absorbing layer."

[Emphasis supplied] [Col. 10, lines 35 to 41]

That portion of Ito et al. teaches that only certain stretched polypropylenes are useful as an impact-absorbing layer.

Ito et al. further states:

"More specifically, as is shown in Example 4, a package formed from a laminate sheet including a polypropylene layer bonded directly to an aluminum foil shows a considerable tendency to break when it is subjected to the falling test in the food-packed state after a retort treatment. Further, even when a resin film having an impact-absorbing coefficient less than 0.5×10^{-4} cm, such as a polyethylene terephthalate film, polyethylene naphthalate film or stretched polyethylene film is interposed between the polypropylene layer and aluminum foil, as illustrated in Fig. 5, the pouch breakage tendency is relatively high. In

contrast, when the film interposed between the polypropylene layer and aluminum foil has an impact-absorbing coefficient of 0.5×10^{-4} cm or more, the average pouch breakage ratio is significantly improved and can be maintained as low as 0.05 or less". [Emphasis supplied] [Col. 10, lines 47 to 63]

That portion of Ito et al. teaches that, when a polypropylene layer or a specific type of stretched polypropylene (under a polypropylene layer) is directly bonded to the metal foil, the pouches have high breakage rates.

One of the advantages of applicants' claimed sterilizable composite film is that it can withstand sterilization conditions, for example, it does not delaminate under sterilization conditions. Applicants have a polypropylene layer directly bonded to the metal foil (or only with an intermediate bonding agent layer or laminate adhesive layer).

The prior art section of Ito et al. discloses that pouches subjected to sterilization conditions cause heat-sealed area failure where there is polypropylene to polypropylene contact or cause delamination between an oriented polypropylene film and a metal foil intermediate layer or an outer heat resistant layer. (Note that in Ito et al. polyamines can be used for the heat resistant outer layer and for the impact-absorbing layer.) This prior art recited by Ito et al. would cause one ordinarily skilled in the art to avoid using a polypropylene layer directly (or through a bonding agent layer or a laminate adhesive layer) to a metal foil because of delamination and/or heat-sealed area failure.

Ito et al. states:

“None of the known inner face-constituting materials meets the above requirements sufficiently. For instance, low density or medium density polyethylene has been used as an inner face-constituting material of a heat-sealable laminate sheet. However, in the case of such polyethylene, considerable amounts of resin-constituting components are extracted and migrate into the food during the high-temperature sterilization. Further, the heat-sealed area fails to resist the high temperature sterilization treatment sufficiently.”

“An oriented polypropylene film (OPP) which is frequently used as a packaging material is considerably superior to polyethylene with respect to the heat resistance, but the range of temperatures at which heat sealing may be carried out is extremely narrow and it is difficult to conduct the heat sealing step on a commercial scale. Further, the heat-sealed area has an extremely poor seal strength and impact resistance after high temperature sterilization in a retort, and the oriented polypropylene film is also defective in that delamination readily occurs between the polypropylene layer and a metal foil intermediate layer or outer heat-resistant layer.”

“There is also known a retortable flexible pouch comprising an undrawn polypropylene film such as a cast polypropylene film as a sealable inner face material of a laminate sheet. This pouch can be used at a low sterilization temperature, for example, 120° C or lower, but during high

temperature heat sterilization conducted at 130° to 150° C the polypropylene inner face layer is readily peeled from the laminate sheet substrate. This is a fatal defect of the container of this type.” [Emphasis supplied] [Col. 2, lines 15 to 46]

Accordingly, the disclosure of Ito et al. directs one ordinarily skilled in the art to avoid using a polypropylene layer directly bonded to a metal foil.

Ito et al. does not specifically describe a functional layer of a first polypropylene layer, a polyamide layer and a second polypropylene, bonded to one side of a metal foil. Such layer arrangement is also not obvious from Ito et al. The invention of Ito et al. involves pouches which can resist high-temperature (i.e., 130° to 150° C) short-time (i.e., 10 to 600 seconds) sterilization. Applicants' pouches unexpectedly can stand sterilization at 130° C without delamination occurring.

Page 11, lines 23 to 25, of applicants' specification states:

“The composite films according to the present can be sterilized without suffering delamination of the individual layers or loss of strength e.g. by a thermal treatment at 110° to 130° C, preferably 121° C, for 10 to 60 minutes, preferably 30 minutes.” [Emphasis supplied]

The Office Action stated that the impact-absorbing layer is a thermoplastic resin having the desired impact properties such as stretched or unstretched polyamides or copolyamides, or stretched polypropylene having the desired impact absorbing coefficient and a melting point higher than the melting point of the polypropylene of (a) (Col. 9, lines 55 to 60; Col. 10, lines 34 to 36). Ito et al.

does not teach or suggest applicants' three layer-second functional layer C, or the unexpected advantage of using it. Further, applicants' claims require coextrusion, coextrusion coating, and/or extrusion lamination.

The Office Action state that the packaging laminate can be formed into bags for food packaging with the layer thickness selected to produce a laminate with the desired properties, with a preferred thickness of 10 to 50 μm for the outer layer, 10 to 50 μm for the oxygen barrier layer or 5 to 20 μm for the aluminum foil layer, and 30 to 100 μm for the heat-sealable polypropylene layer (a) and 5 to 40 μm for each impact-absorbing layer (Col. 12, lines 7 to 36). Ito et al. does not teach or suggest applicants' three layer second functional layer C, or the unexpected advantage of using it. The scope of the thermoplastic resins designated by Ito et al. as usable for its impact-absorbing layer is immense. No motivation to choose applicants' layers and sequence thereof is present.

The Office Action stated that, although Ito et al. teaches that other polymers may be utilized for different layers other than the instantly claimed polymers, Ito et al. does disclose the polymers instantly claimed in the order as instantly claimed, and it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize any of the polymers or polymer disclosed by Ito et al. in the disclosed combinations to produce a multilayer composite. Applicants traverse this statement as being mere speculation. Ito et al. does not suggest or specifically disclose applicants' claimed invention. There is no motivation of record to try to piece together parts of Ito et al. to come up

with applicants' claimed invention. The burden of proof under Section 103(a) is upon the Examiner, and the use of forbidden hindsight does not fulfill the burden.

The Office Action stated that Ito et al. does not teach the particular thickness ranges as instantly claimed, however, it is well known in the art that the thickness of a particular layer in a multilayer composite is a result-affected variable affecting film properties such as gas and water-vapor permeability, heat-resistance, flexibility and sealing properties, and therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize routine experimentation to determine the optimum thickness for composite layer(s) based on the desired film properties required for a particular end use. Applicants traverse this statement as being speculation. Section 103(a) requires facts.

The Office Action stated that, further, in producing multilayer composites, the use of lamination, extrusion-coating or coextrusion or combinations of these methods, with or without an adhesive between adjacent layers, are conventional and well known in the art and any combination of these methods in producing the multilayer composite taught by Ito et al. would have been obvious to one having ordinary skill in the art at the time of invention. This statement is also mere speculation

This rejection should be withdrawn.

Reconsideration, reexamination and allowance of the claims are requested.

U.S.S.N. 09/505,713
Amendment



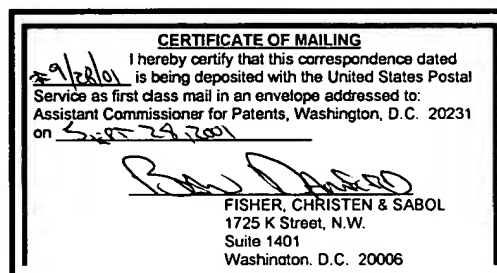
Respectfully submitted,

Virgil H. Marsh

Virgil H. Marsh
Registration No. 23,083

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FISHER, CHRISTEN & SABOL
1725 K Street, N.W.
Suite 1401
Washington, D.C. 20006
Telephone: 202/659-2000
Facsimile: 202/659-2015



VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claim 15 has been amended as follows:

15. (Twice Amended) A sterilizable composite film containing a barrier layer that is impermeable to water vapor and gases comprising a metal foil and on both sides of the barrier layer at least one functional layer, the composite film having a layer structure containing one on top of the other in the following sequence:

(a) a first functional layer containing a plastic film that is a polyester, a polyamide, or a polyolefin, or an extrusion layer of a polyolefin, or one or more lacquer layers, or print and lacquer layers, or print layers;

(b) a metal foil having a thickness of 5 to 100 μm ; and

(c) a second functional layer containing a plastic layer that is a layer comprising a coextrusion-coated, a coextruded, and/or an extrusion-laminated film having a sequence of a first polypropylene layer, a polyamide layer, and a second polypropylene layer [.]

said first polypropylene is directly bonded to metal foil (b) or is bonded to metal foil (b) by means of a bonding agent layer or a laminate adhesive layer, and, optionally, a primer layer is on at least one surface of metal foil (b).

Claim 19 has been amended as follows:

19. (Twice Amended) The sterilizable composite film according to Claim 18, wherein the second functional layer (c) comprises a film having a sequence of a [coextension] coextrusion coated first bonding agent layer, a first polypropylene layer, a second bonding agent layer, a polyamide layer, a third

bonding agent layer, and a second polypropylene layer, the first bonding agent adhering together the metal foil (b) and the second functional layer (c).

New Claims 36 and 37 have been added.